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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/713,498	11/15/2000	Chaoying Zhao	014938.0003	4672

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EXAMINER

PAK, JOHN D

ART UNIT PAPER NUMBER

1616

DATE MAILED: 03/19/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/713,498

Applicant(s)
ZHAO

Examiner
John Pak

Art Unit
1616



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 2, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-37 is/are pending in the application.
- 4a) Of the above, claim(s) 23, 24, 29, and 31-34 is/are withdrawn from consideration
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-22, 25-28, 30, and 35-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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Claims 20-37 are pending in this application.

The claims in this application are still under an election of species requirement. The presently elected and expanded species under examination is NaCl + hydroxyethyl starch. Accordingly, claims 23-24, 29 and 31-34 are withdrawn from further consideration as being directed to non-elected subject matter. Claims 20-22, 25-28, 30, 35-37 will presently be examined to the extent that they read on the above noted expanded elected subject matter.

Claims 20-22, 25-28, 30, 35-37 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. On specification page 5, paragraph 0015, applicant discloses that the total sodium concentration must not be more than that of 6.9% NaCl solution or equivalent. This feature is critical or essential to the practice of the invention but is not included in the claims; therefore the claims are not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Claim language in claims 26 and 37 are noted, but there, the sodium concentration is limited only to two ingredients, whereas the original disclosure limited the sodium concentration for the whole composition.

Claims 20-22, 25-28, 30, 35-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 20-22, 25-28, 30, 35-36 recite or read on an "L-arginine free" pharmaceutical composition. This feature was not conveyed by the originally filed disclosure. Mere absence of

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a substance from the disclosure does not necessarily support its explicit exclusion in claim language. As in any new matter analysis, the originally filed disclosure must have reasonably conveyed the exclusion. In the present case, there is no indication from the originally filed disclosure that another beneficial agent in shock treatment such as L-arginine must be excluded.

Applicant is advised that the new matter without adequate descriptive support, the L-arginine free feature, necessitates the non-application of WO 98/0850 with respect to claims 20-36. Should applicant amend the claims to remove the new matter, applicant is given notice herein that the reference would then be applicable to said claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 37 is rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/08500.

WO 98/08500 explicitly discloses a hypertonic composition comprising L-arginine, NaCl (including 6 wt%, see claim 14) and hetastarch (hydroxyethyl starch, minimum 5 wt%, see Table 3 and claim 10 and 11). See claims 1-3, 6-7, 10-11 and 13-14. Most convenient mode of administration is by injection (p. 5, lines 1-2).

Claim 37 is open to 0% "second substance," so the second substance feature is met by the cited reference. Claim 37 requires an injection present in an amount of 76.1-95.5 w/v%. Since

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the injection mode of administration is clearly disclosed, an injectable preparation with water or other suitable injectable preparation to deliver the actives is clearly and necessarily disclosed by the cited reference. The specifics of 76.1-95.5 w/v% is obtained from the cited reference: after the L-arginine, NaCl and hydroxyethyl starch amounts are taken into account, the injection amount is the remainder and falls within the claim scope. The feature of total sodium ion not exceeding an equivalent sodium concentration in a 6.9 w/v% sodium chloride solution is noted, but the cited reference expressly encompasses compositions that do not contain other significant sources of sodium. See claim 14. The claim is thereby anticipated. In re Sivaramakrishnan, 213 USPQ 441 (CCPA 1982).

Claim 20 is rejected under 35 USC 102(b) as being anticipated by Chemical Abstracts 121:49804.

Chemical Abstracts 121:49804 explicitly discloses a 7.2 % NaCl + 10% hydroxyethyl starch solution for physiological use.

Applicant's claim 20 requires sodium chloride in an amount between about 1.5% and 6.9%. The prior art 7.2% NaCl is within the scope of "about" 6.9%. Percent basis of w/v is understood from the conventional practice of disclosing weight per volume in this field. The disclosed formulation is presumed to be sterile enough to be used as an injection because of its physiological use. The claims are thereby anticipated.

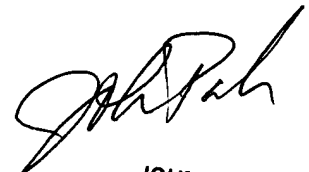
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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner Pak whose telephone number is (703) 308-4538. The Examiner can normally be reached on Monday through Friday from 7:30 AM to 4 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.



JOHN PAK
PRIMARY EXAMINER
GROUP 1600